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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,403	07/08/2003	Joe W. Gray	023070-139300US	9224

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/616,403	Applicant(s) GRAY ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-III. Claims 1-6, drawn to a method of detecting a breast cancer cell in a biological sample comprising contacting the sample with a polynucleotide that hybridized to a nucleic acid sequence encoding a polypeptide, SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6, respectively, classified in class 435, subclass 6.

IV-VI. Claims 7-9, drawn to a method of detecting a breast cancer cell in a biological sample comprising detecting an increase in the level of a polypeptide, SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6, respectively, classified in class 436, subclass 86. Claim 9 will be examined with this Group to the extent the level of a polypeptide is detected.

VII-IX. Claim 9, drawn to a method of monitoring the efficacy of a therapeutic treatment of cancer comprising detecting the level of a polynucleotide that encodes SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6, respectively, in a biological sample, classified in class 436, subclass 174. Claim 9 will be examined with this Group to the extent the level of a polynucleotide is detected.

X-XII. Claim 10, drawn to a method for identifying a compound that modulates a breast cancer-associated polypeptide comprising contacting the compound with a polypeptide, SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6, respectively, classified in class 530, subclass 350.

Art Unit: 1643

XIII-XV. Claims 11-14, drawn to a method of inhibiting proliferation of a breast cancer cell that overexpresses a polypeptide having an amino acid sequence, SEQ IDNO: 2, SEQ ID NO: 4 or SEQ ID NO: 6, respectively comprising contacting the cancer cell with a therapeutically effective amount of an inhibitor, classified in class 424, subclass 130.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different method inventions of Groups I-XV implement different and distinct polynucleotides, which encode different and distinct polypeptides. Each polynucleotide encodes a different product. Specifically, SEQ ID NO: 2 is a Bcl2-associated athanogene 4 (BAG4), Silencer of Death Domains (SODD), which is 457 amino acids. SEQ ID NO: 4 is a ADP-ribosylation factor-I (ARF1), which is 181 amino acid residues, whereas SEQ ID NO: 6 is a Ephrin Receptor A2 (EPHA2), Epithelial Cell Receptor Protein-Tyrosine Kinase (ECK) consisting of 976 amino acid residues.

However, BAG4 is also known as Silencer of Death Domains (SODD) and involved in apoptosis. ARF1 is a small guanine nucleotide-binding protein that is a member of the RAS superfamily and is involved in vesicular transport and activates phospholipase D. These functions are tied to its ability to reversibly associate with membranes, interact with phospholipids, and the hydrolysis of GTP. And EPHA2 is a

Art Unit: 1643

member of the EPH and EpH-related receptor subfamily of receptor protein-tyrosine kinases. Accordingly, by virtue of the functional and structural differences between the three polypeptides all the methods (Groups I-XV) implementing the polypeptides are different and distinct and are not useable together or capable of being searched together.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Art Unit: 1643

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

22 May 2006